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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,826	02/08/2002	Mitchell F. Brin	17326CIP2 (BOT)	2841
51957	7590	01/06/2010	EXAMINER	
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1643	
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			01/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/071,826	Applicant(s) BRIN ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 26, 2009 has been entered.

2. Claims 11 and 34-44 are pending.

Claims 35 and 36 have been amended.

Claims 11 and 34-44 are examined on the merits.

Withdrawn Objections

Specification

3. The disclosure is no longer objected to because word, "hyperplasic" has been replaced with the proper word, "hyperplastic".

Claim Objections

4. Claims 35 and 36 are no longer objected to because the word, "hyperplasic" has been replaced with the proper term, "hyperplastic".

Maintained Rejection

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claims 11 and 34-44 under 35 U.S.C. 103(a) as being unpatentable over Aoki et al./ U.S. Patent Application Publication 2001/0043930 A1 (effective filing date December 28, 1993), and further in view of Wald and Kakulas (The Australian and New Zealand Journal of Surgery 33(3): 200-204, February 1964) and Donovan/ U.S. Patent number 6,312,708 (filed July 21, 2000) as evidenced by Vakil et al. (C. M. A. Journal 109: 29-32, July 7, 1973) is maintained.

Applicants argue the Office has not met its burden of establishing a *prima facie* case of obviousness and details why they believe this is the case, see Remarks submitted October 26, 2009, beginning on page 14, section II. Applicants also note the criteria the Office must meet in order to establish a rejection under obviousness, see Remarks, page 15. Applicants discuss each reference separately, as well as in combination, see Remarks, pages 15-18. These points of view and arguments have been carefully considered, but found unpersuasive.

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Applicants assert Aoki's cholinergic-controlled secretions or mucus secretions do not overlap with the definite substance described in the Wald reference. The Examiner regards this characterization as an opinion and not a scientific fact predicated upon science. The substance taught in Wald reads on the secretion released from the atypical tissue of a mammary gland. Applicants support their arguments noting the evidentiary reference, Vakil does not teach or suggest the treatment of a mammary gland disorder or secretions form atypical tissue in mammary glands, see Remarks, page 16. The Examiner does not rely upon Vakil for the said treatment, but rather evidence that secretions are emitted from mammary glands of the apocrine type, see Vakil page 31, 2nd column. The Examiner knows the three criteria necessitated to establish a *prima facie* case of obviousness. In summary, there must be some suggestion or motivation; a reasonable expectation of success; and the prior art references must teach or suggest all the claim limitations. Aoki teaches treating various disorders with botulinum toxins and suggests modifications can be made. Moreover, Aoki teaches the local administration of botulinum toxin type A to a patient suffering from a disease or conditions such as excessive sweating, lacrimation and mucus secretions, see abstract; page 1, section 0014; page 2, section 0017; and page 4, Example 5. Wald teaches apocrine gland carcinoma of the breast, which releases a substance, see page 203, column 1, last

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paragraph. The Donovan patent teaches a biodegradable polymer implant capable of releasing botulinum toxin A in variable amounts for various disease conditions with success, see column 16, lines 53-60; and bridging paragraphs of columns 25 and 26.

Consequently, one of ordinary skill in the art would have been motivated with a reasonable expectation of success to treat the said mammary gland disorder with botulinum toxin type A. The Examiner has met all three criteria for establishing a *prima facie* case of obviousness. For the reasons of record and listed herein the rejection is maintained.

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a *flexible schedule*, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
04 January 2010
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643